A Prospective, Randomized Clinical Trial to Assess the Cost-effectiveness of a Modern Foam Dressing versus a Traditional Saline Gauze Dressing in the Treatment of Stage II Pressure Ulcers

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Abstract
Modern dressings such as hydrocolloids, gels, and foams are typically more expensive than traditional dressings such as gauze. However, if modern dressings require fewer changes, the overall cost of treatment may be lower despite the higher initial purchase price. If healing rates are comparable or better, modern dressings also may be cost-effective. A 4-week, prospective, randomized clinical trial to assess differences in treatment costs and cost-effectiveness between a modern foam dressing and saline-soaked gauze was conducted among 36 patients (22 men, 14 women, mean age 72.8 years) with a Stage II pressure ulcer (mean duration 35 weeks) at five centers in the United States. Participants were randomized to treatment with a self-adhesive polyurethane foam (n = 20) or saline-soaked gauze dressing (n = 16). No difference in time to wound closure was observed (P = 0.817). Patients in the foam group had less frequent dressing changes (P <0.001). Total cost over the study period was lower by $466 per patient (P = 0.055) and spending on dressings was lower by $92 per patient in the foam group (P = 0.025). Cost per ulcer healed was lower by $1,517 and cost per ulcer-free day was lower by $80 for patients in the foam group. On the evidence of this study, the foam dressing is a more cost-effective treatment than saline-soaked gauze for the treatment of Stage II pressure ulcers.

Key Words: wound healing, pressure ulcer, dressings, occlusive, cost effectiveness

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Two studies published in the 1960s demonstrated that a moist wound environment is associated with quicker healing than an environment where a wound is allowed to dry through exposure to the air. In principle, traditional dressings such as gauze can provide an appropriate wound environment providing they are kept moist, usually by adding saline. To keep the wound from drying out, saline-soaked gauze normally is changed at least daily. Modern dressings such as hydrocolloids, foams, and hydrogels have been designed to provide improved moisture handling properties that make it possible to maintain a moist wound environment without the need for daily dressing changes.

The evidence base in wound care generally is poor. Several recent reviews have highlighted the fact that there is little compelling evidence of a significant difference in time to healing or percent healed when comparing patients treated with traditional
versus modern dressings. The per-unit price of modern dressings tends to be higher, which may explain why traditional products are still commonly used in routine clinical practice.

However, healing is not the only relevant end point in a comparison between treatments that differ not only in the type of dressing used, but also in the frequency of dressing changes. Frequency of dressing change has a direct impact on the amount of nurse time required for a given treatment period and on the quantities and cost of dressings and other materials. Even in the absence of evidence of a difference in time to healing, costs per patient may be lower using a more expensive dressing if the frequency of dressing change is lower. But neither cost nor healing alone can inform an appropriate treatment choice. Cost-effectiveness involves both costs and patient outcomes, combined in a measure of cost per ulcer healed or cost per healed day.

A prospective, randomized clinical study was conducted to 1) evaluate the difference in treatment costs between a care regimen involving use of an advanced self-adhesive foam dressing and a treatment regimen involving use of a lower-priced traditional gauze dressing and 2) compare the relative cost-effectiveness of the two treatment regimens in patients with a Stage II pressure ulcer.

The authors believe this is the first randomized, controlled study comparing a modern foam dressing with saline-soaked gauze in patients with a pressure ulcer and the first to explicitly evaluate the cost-effectiveness of a modern wound dressing. Other studies have reported differences in healing and treatment costs between patients with a pressure ulcer treated with a hydrocolloid dressing and a control group treated with saline-soaked gauze. One randomized study compared a moisture vapor-permeable dressing (MVP) with gauze and tape in the treatment of patients with a pressure ulcer, and a prospective study evaluated cost-effectiveness of a treatment regimen that included a combination of modern dressings and a defined treatment algorithm. In most of these studies, cost-effectiveness was not formally evaluated.

Methods

Institutional Review Board (IRB) approval was obtained from each of the five participating study centers. Study centers provided wound care in hospital inpatient wards (three centers), a hospital-based outpatient clinic (one center); a long-term residential care (one center), and a community-based wound clinic (one center). The patient or his/her legal representative, guardian, or caregiver was fully informed of the nature of the evaluation and given adequate time (at least 24-hours) to read and consider the patient information sheet before agreeing to give written consent to participate in the study. The date the patient was given the information sheet and the date consent was obtained were recorded in the patient notes and the evaluation screening log.

Inclusion/exclusion criteria. Participants had to be at least 18 years of age; either gender; not pregnant or (if of appropriate age) using contraception; and have a Stage II pressure ulcer (according to the National Pressure Ulcer Advisory Panel [NPUAP] classification system) with slight to moderate levels of exudate. If a patient had more than one eligible wound, the largest wound was selected to receive the study treatment. Patients with a known history of poor compliance; presence of clinical infection in the wound; presence of Stage I, Stage III, or Stage IV pressure ulcers; and previous participation in the evaluation were excluded.

All new and existing patients who met the eligibility criteria between November 2005 and March 2007 were screened for inclusion in the study. Consenting patients were assigned a sequential patient number at each study center. A randomization schedule determined treatment allocation to either self-adhesive polyurethane foam dressing (Allevyn Thin, Smith & Nephew Inc, Largo, FL) or saline-soaked gauze. The products used in this evaluation both are indicated for use in patients with a pressure ulcer.

Sample size. The a priori sample size calculation determined that 19 patients in each group would be required to detect a $10 per week difference in the cost of dressings and other materials between groups, assuming a common standard deviation of $9.80. This was estimated on the basis of a two-sided unpaired Student’s t-test at the 5% level of significance and 80% power. In order to allow for patient dropout, the target was to recruit at least 25 patients per group. Because patient recruitment was slower than expected, recruitment was stopped after 36 patients had been enrolled.

Clinical procedure. In both treatment groups the wound was cleansed, dried, and prepared according to local procedures (which may have differed between study centers). Wounds in the gauze group were dressed with saline-soaked gauze covered with a dry sterile gauze pad held in place with tape (a secondary dressing was placed if required). Wounds in the foam group were dressed with the self-adhesive dressing without need for a secondary dressing or additional fixation. In both study groups, dressing...
change frequency was determined at the discretion of the clinical investigator.

Patients were assessed weekly for up to 4 weeks or until wound healing, whichever occurred first. Weekly assessments recorded details of wound healing and dressing changes (time and materials used). Dates of dressing changes carried out between weekly assessments were recorded in the patient's diary booklet. Wound area was measured at baseline and weekly using Visitrak (Smith & Nephew Inc, Largo, FL). Study participants were not blinded.

Outcome measures. Outcomes were time to heal, incidence of clinical infection, and treatment cost (materials cost and total cost measured separately). Derived measures used in the cost-effectiveness analysis were cost per patient, cost per ulcer healed, and cost per ulcer-free day.

Resource costs. The perspective of the analysis was cost to the healthcare provider of dressings, other materials, and nurse time used to dress the study ulcer over a continuous 28-day treatment period or until healing. Resource use was recorded prospectively for each patient (covering dressings and other materials used, type and grade of staff, number of staff, and time required for each dressing change). Resources were valued using representative national prices in the US at mid-2007 and national US hourly wage rates of nurses and nurse assistants at May 2006.15 The price of the foam dressing was the average US retail price and the prices of other materials (gauze, saline, fixing tape, gloves, syringes) were taken from a web-based surgical supplies company16 (see Table 1). Costs were not discounted.

Statistical analysis. Details of wound healing and dressing changes at each assessment were recorded by the study investigator directly to a case report form (CRF). Data entry and statistical analysis were performed by the Health Economics and Outcomes Research department at Smith & Nephew Advanced Wound Management.

With the exception of the cost analysis, all data analysis was conducted on the full analysis data set, defined as all patients who had a Stage II pressure ulcer (slightly to moderately exuding) and an initial baseline assessment. Two patients in the foam group had no information recorded on dressing changes between weekly assessments. These patients were included in the full analysis data set, but because it is likely these patients had additional dressing changes that were not recorded, including costs for these patients may have led to an underestimation of average treatment costs for patients in the foam group. For this reason, these patients were excluded from the costing analysis.

In the primary analysis, a two-sample Student’s t-test was used to test for a difference in the material cost per patient per week between treatment groups. Secondary analyses were carried out

Table 1: Resource Prices in the United States at Mid-2007

<table>
<thead>
<tr>
<th>Resource</th>
<th>Cost $</th>
<th>Unit cost $</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allevyn Thin 5 cm x 6 cm</td>
<td>$24.91 per box of 10 dressings</td>
<td>$2.49*</td>
<td>Sterile conforming for gauze 2” x 4.1 yd (per 12)</td>
</tr>
<tr>
<td>Allevyn Thin 10 cm x 10 cm</td>
<td>$27.88 per box of 5 dressings</td>
<td>$5.58*</td>
<td>Sterile conforming gauze 4” x 4.1 yd (per 12)</td>
</tr>
<tr>
<td>Sterile gauze 2” x 2”</td>
<td>$5.95 (per 12)</td>
<td>$0.50*</td>
<td></td>
</tr>
<tr>
<td>Sterile gauze 4” x 4”</td>
<td>$8.45 (per 12)</td>
<td>$0.70*</td>
<td></td>
</tr>
<tr>
<td>Kendall saline</td>
<td>$1.65 per 100 mL bottle</td>
<td>$0.017 (per mL)*</td>
<td>5-cc syringe, box of 100</td>
</tr>
<tr>
<td>Syringes</td>
<td>$22.95 (per 100)</td>
<td>$0.23*</td>
<td></td>
</tr>
<tr>
<td>Gloves (pair)</td>
<td>$39.95 (per 50 pair)</td>
<td>$0.80*</td>
<td>Sterile, nonlatex exam gloves, box of 50</td>
</tr>
<tr>
<td>Tape (inches)</td>
<td>$3.60</td>
<td>$0.051 (per inch)*</td>
<td>Omniflex nonwoven retention tape 2” x 2 yd</td>
</tr>
<tr>
<td>Registered nurse (RN)</td>
<td>$27.54/hour</td>
<td>$0.46/minute*</td>
<td>Median hourly wage of a registered nurse (May 2006)</td>
</tr>
<tr>
<td>Licensed practical nurse (LPN)</td>
<td>$17.57/hour</td>
<td>$0.29/minute*</td>
<td>Median hourly wage of a licensed practical nurse/licensed vocational nurse (May 2006)</td>
</tr>
<tr>
<td>Assistant/Auxiliary</td>
<td>$17.57/hour</td>
<td>$0.29/minute*</td>
<td>Same as LPN</td>
</tr>
</tbody>
</table>


15 US Bureau of Labor Statistics15
Results

Thirty-six inpatients and outpatients (22 men, 14 women, mean age 72.8 years, mean ulcer duration 35 weeks, mean ulcer size 5.9 cm²) who met the criteria were recruited from the five study centers. Ulcers were located on the hip/buttocks (14), sacrum (15), upper leg (one), ankle/foot (five), and lower leg (one) (see Table 2). Because of the presence of extreme outlying values for some of the baseline variables (such as ulcer duration), it is more appropriate to consider median rather than mean values of these variables. Median ulcer duration was longer in the foam group (3.5 weeks versus 2.0 weeks) and median ulcer area was larger (1.8 cm² in the foam group versus 1.4 cm² in the gauze group).

The 36 study participants were randomized to receive treatment with a self-adhesive polyurethane foam (n = 20) or saline-soaked gauze dressings (n = 16). Nine patients were withdrawn from the study — six in the foam group (three died, one developed a wound infection, one developed an abscess unrelated to the study wound, and one became ineligible for other reasons) and three in the gauze group (two died and one asked to be discharged from the hospital). An additional two patients with infected wounds at the screening assessment were consented in error; neither of these patients was randomized.

Cost per week. The mean weekly cost of dressings and other materials was significantly lower in the foam group (P = 0.014). The mean saving was $26 per patient (95% CI = $5.7, $46.3). Materials cost was $32 per patient per week in the foam group compared with $58 in the gauze group. Total cost per week also was significantly lower in the foam group (P = 0.038). The mean savings was $118 per patient (95% CI = $13, $223). Total cost was $91 per patient in the foam group compared with $209 in the gauze group (see Table 3).

The driver of lower cost per week was the lower frequency of dressing change in the foam group. Patients in the foam group had a mean of 4.9 dressing changes per week compared with a mean of 12.9 changes per week in the gauze group (P <0.001).

Time and cost to healing. There was no evidence of a difference in the time to wound closure between the two treatment groups (P = 0.817). The Kaplan-Meier estimate of the median time to healing (time at which 50% of patients are healed) was 28 days in both treatment groups. Cost to healing was 44% lower in the foam group (P = 0.098).

Cost-effectiveness. Table 4 shows costs and outcomes for the two treatment groups over the full 28-day study period. In this main analysis, treatment costs were recorded until the end of the study (at ulcer healing or 28 days, whichever occurred first). For
patients who withdrew early before healing, costs were imputed assuming they would have continued treatment to the end of the study period. Nine patients (six from the foam group and three from the gauze group) withdrew early from the study. This analysis represents an upper-bound on costs for these patients because it assumes none would have healed during the study period.

Total cost per patient over the 28-day treatment period was $315 in the foam group compared with $781 in the gauze group, representing a mean saving of $466 per patient for the foam group ($P = 0.055; 95% CI = $22, $911). Spending on dressings and other materials was $92 per patient lower in the foam group ($P = 0.025; 95% CI = $12, $171).

Lower costs do not necessarily mean that a treatment is more cost-effective. Costs must be linked to patient outcomes. Ten patients in the foam group (50%) were healed within the 28-day study period compared with six (38%) in the gauze group. The mean time free of ulcer (days healed) was 9.3 days per patient in the foam group compared with 6.9 days in the group treated with gauze.

In this analysis, cost-effectiveness was measured by cost per ulcer healed and cost per ulcer-free day. Cost per ulcer healed was lower in the foam group by $34 ($114 compared with $148) and cost per ulcer-free day was lower by $80 ($34 compared with $114). On this basis, the foam dressing represents a more cost-effective treatment choice.

The costs and outcomes observed in the trial provide the best evidence available on which to form a judgment about the relative cost-effectiveness of the two treatment options. The analysis shows that overall costs are lower in the foam group and that on both measures of cost-effectiveness (cost per ulcer healed and cost per ulcer-free day), the foam option is dominant. The study was not powered to detect a difference in time to healing and although a difference favoring the foam group was observed, this difference was not statistically significant at the 5% level.

**Infection.** No evidence of a higher level of infection was noted in either of the study treatments. One patient (5%) in the foam group showed clinical signs of infection in the reference wound and was withdrawn from the study. No patients in the gauze group showed signs of infection. No adverse device events were reported during the study.

**Sensitivity analysis.** For patients who withdrew early (before their wounds healed or before the end of the treatment period), costs were included to the point of withdrawal, but no additional costs were imputed to cover the remaining time to the end of the study. This analysis represents a lower-bound to the estimate of treatment costs for the nine patients who withdrew before healing because it assumes those patients incurred no further treatment costs during the study period.

This assumption made no material difference to the conclusions of the analysis. Under this assumption, the mean saving in total cost per patient was $435 in favor of the foam group ($P = 0.076; 95% CI = $16, $886) compared with a mean saving of $466 in the main analysis. The mean saving on materials was $87 per patient in the foam group ($P = 0.025; 95% CI = $11, $163) compared with a mean saving of $92 in the previous analysis. Cost per ulcer healed and cost per ulcer-free day are both lower in the group treated with the foam dressing (by $1,382 and $73, respectively).

**Discussion**

The results of this study show that despite the lower initial price of gauze dressings, a treatment regimen involving saline-soaked gauze is both more expensive and less cost-effective than a regimen involving use of a modern polyurethane foam. Expenditure on dressings and other materials was lower by $26 per patient per week in the group treated with foam, with similar or better rates of healing. In practice, this translates to the potential to treat 80% more patients ($58.2/$32.2; see Table 3) with the same materials budget despite the higher unit cost of dressings. The cost of nurse time was lower by an average of $92 per patient per week. At a median hourly wage of $27.54 (see Table 1), this means approximately 3 hours of Registered Nurse (RN) time per patient per week is available for other duties. Every 12 wound patients switched from gauze to foam releases the equivalent of 1 full-time RN per week.

The results of this study are consistent with the majority of previous randomized studies that compared costs and healing in patients with a pressure ulcer treated with a modern dressing (usually hydrocolloid) or saline-soaked gauze. The authors are not aware of any other studies that included a foam dressing. Xakellis and Chrischilles randomized 39 patients with pressure ulcers in long-term care to treatment with hydrocolloid dressings (18 patients, mean age 77.3 years) or nonsterile saline-gauze wet-to-moist dressings (21 patients, mean age 83.5 years). They found no statistically significant difference in healing between treatment

### Table 4: Treatment Cost and Patient Outcomes in the Study Period

<table>
<thead>
<tr>
<th></th>
<th>Polyurethane foam</th>
<th>Saline-soaked gauze</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample size</td>
<td>18</td>
<td>16</td>
</tr>
<tr>
<td>Total treatment cost</td>
<td>$5,667</td>
<td>$12,500</td>
</tr>
<tr>
<td>Materials</td>
<td>$2,057</td>
<td>$3,294</td>
</tr>
<tr>
<td>Nurse time</td>
<td>$3,610</td>
<td>$9,206</td>
</tr>
<tr>
<td>Patients healed by day 28</td>
<td>10</td>
<td>6</td>
</tr>
<tr>
<td>Ulcer-free days per patient</td>
<td>9.3</td>
<td>6.9</td>
</tr>
<tr>
<td>Cost per patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Materials</td>
<td>$315</td>
<td>$781</td>
</tr>
<tr>
<td>Nurse time</td>
<td>$114</td>
<td>$206</td>
</tr>
<tr>
<td>Cost per ulcer healed</td>
<td>$567</td>
<td>$2,083</td>
</tr>
<tr>
<td>Cost per ulcer-free day</td>
<td>$34</td>
<td>$114</td>
</tr>
</tbody>
</table>

* Two patients were excluded from the costing analysis because of missing data.
groups and the difference in cost per patient was sensitive to the choice of nurse wage rates — cost savings with hydrocolloid dressings reached statistical significance with national but not local wage rates. Colwell et al\textsuperscript{10} randomized patients with a Stage II or Stage III pressure ulcer to treatment with a hydrocolloid dressing (33 patients, mean age 68 years) or moist gauze dressings (37 patients, mean age 68 years) and found more patients healed in the hydrocolloid group (22% versus 2%) at a lower cost per day. Chang et al\textsuperscript{11} randomized 34 hospital patients (mean age 58 years) with Stage II or Stage III pressure ulcers to treatment with a hydrocolloid dressing or saline gauze. They found no statistically significant difference in total treatment costs between groups and no statistically significant difference in wound area reduction over a maximum of 8 weeks (this study did not measure complete healing). In a prospective study, Sebern\textsuperscript{12} randomized 48 patients with 77 grade II or grade III pressure ulcers treated in home care to treatment with gauze and tape or a transparent moisture vapor permeable dressing (MVP) and concluded that the MVP dressing improved healing over an 8-week period and was more cost-effective for grade II ulcers. Ohura et al\textsuperscript{13} compared three treatment regimens: modern dressings with a treatment algorithm, traditional care (ointment and gauze) used with a treatment algorithm, and traditional care used without a treatment algorithm. They reported that modern dressings used with a treatment algorithm were more cost-effective than either of the comparators.

The main determinant of cost-effectiveness in the present study was the lower frequency of dressing change observed in the foam treatment regimen. This is consistent with other studies. A recent review\textsuperscript{18} of literature on the relative cost-effectiveness of modern dressings compared with traditional dressings in patients with a pressure ulcer identified 14 studies reporting a comparison of dressing change frequency. In these studies, the frequency of change for traditional (gauze) dressings ranged from seven to 28 per week, with a mean of 15 per week (median = 14). In the current study, the mean number of changes was 12.9 per week in the gauze treatment group (median = 13.8). The frequency of change for modern dressings ranged from 1.4 to seven per week, with a mean of 2.5 per week (median = 2). In the current study, the mean was 4.9 changes per week in the foam treatment group (median = 3.9).

Limitations

The results of this study are sensitive to the relative prices of materials in the two treatment groups and also to the difference in the frequency of dressing change, both of which may vary between centers in the US and between countries. Nonetheless, even if local prices differ substantially from the ones used here, the qualitative result will remain the same as long as the reduction in dressing change frequency is sufficient to offset the additional cost of the more expensive dressing. This study relates to patients treated in a hospital or in an outpatient setting and results may not be generalizable to other care settings such as home care. Wound preparation (cleaning and drying the wound) was not standardized and each patient was treated according to the normal practice of the study center where recruited. It is possible that differences in wound preparation may have impacted healing but because the preparation regimen was common to all patients treated at a particular center, it should have impacted both of the study groups equally.

Ideally, a measure of patient-assessed quality of life should have been included in order to ensure that the cost-effectiveness of the foam dressing is not associated with a lower quality of life. No evidence was found to suggest this possibility, and reducing the risk of wound trauma by reducing the frequency of dressing change is more likely to improve quality of life.

Although the sample size is relatively small in terms of the number of patients recruited, the study provided information on up to 144 weeks of treatment (36 patients × 4 weeks study duration) and up to 1,200 dressing changes. The study was powered to detect a difference in weekly treatment cost and the sample size was adequate to demonstrate a statistically significant difference in this outcome.

Conclusion

A prospective, randomized clinical trial conducted to compare the cost-effectiveness of using a self-adhesive foam versus saline-soaked gauze dressings to treat Stage II pressure ulcers found no significant evidence of a difference between treatment groups in time to healing. However, treatment with foam dressings resulted in a significant saving in treatment costs compared with traditional gauze dressings without adversely affecting healing. Based on the results of this study, a treatment regimen involving use of an advanced foam dressing rather than a lower-priced traditional dressing should be considered.

References